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From: Timperi, Ralph (DPH)
Sent: Monday, March 28, 2005 10:50 AM
To: George, Harvey (DPH); DiNatale, Margaret (DPH); Tisei, Nancy (DPH); Caloggero, Dina (DPH)
Cc: Belanger, Peter (DPH); Borne, Alan (DPH); Elvin, Paul (DPH); Fontana, John (DPH); Gauthier, Cheryl (DPH); Grazioplene, Mariah (DPH); Han, Linda (DPH); Konomi, Raimond (DPH); Nassif, Julianne (DPH); Nawn, Kathleen (DPH); Peppe, Joseph (DPH); Pribeck, Kristen (DPH); Salemi, Charles (DPH); Sloutsky, Alex (DPH); Smole, Sandra (DPH); Werner, Barbara (DPH)
Subject: FW: [aphl-sld] CMS/CLIA Issues Utah Response

FYI, on recent CLIA inspections. R

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-----Original Message-----

From: Barbara Jepson [<mailto:bjepson@utah.gov>]
Sent: Monday, March 28, 2005 10:03 AM
To: State Laboratory Directors' List
Subject: Re: [aphl-sld] CMS/CLIA Issues Utah Response

Paul & others,

Utah just went through a very rigorous CLIA inspection and have been laboriously revamping our QA and QC systems and processes to be in total compliance. In fairness to CMS and our inspector, we were warned that this would be a rigorous inspection. Our lab looked upon it as a chance to improve process. After our inspection we were pretty disheartened. We thought we had a fairly good process in place. Not a perfect system, granted. When we got our deficiency report back it seemed like we hadn't done anything right. It was a big blow. To the credit of our inspector and with our lab's own CLIA personnel, we all sat down and talked about what the write-up of deficiencies actually meant. The reporting process for CMS-CLIA leaves a lot to be desired but our interaction with our inspector was the most important part. She explained what everything meant and that we weren't total failures. She explained how she had seen tremendous improvement in our lab over the prior four years. The end result-our staff worked extremely hard to correct our deficiencies. Careful communication with our inspector and a willingness on the part of our staff to see the processes that could be improved has resulted in better quality work and processes for our lab.

Does the CLIA inspection process need to be improved-Yes.

Most inspectors are doing the best they can in a very bureaucratic organization. Utah, part of Region VIII, is lucky to have the inspector we have. I have had some pretty difficult personalities that come with some inspectors (our Select Agent inspectors, for one. That's why Dr.Brokopp went back to CDC to try and help fix the system. Utah's experience with their SAP inspectors was the worst possible inspection ever).

Thanks to APHL and laboratory colleagues for efforts to improve these burdensome inspection processes.

Barb

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>>> PKimsey@dhs.ca.gov 3/25/2005 1:51:07 PM >>>

Dear Colleague State Public Health Laboratory Directors:

I am writing to ask for information; the APHL board has learned of a number of unsettling interactions with CMS/CLIA over the past few months and we are in the process of setting up an executive committee call to discuss the issue(s).

I am looking for useful examples to express our concerns. What would be helpful are short factual statements regarding attitudes of inspectors, historically unusual citations or significant expenses incurred to come into compliance. Please send your comments to me by email ASAP; staff will work with me to consolidate the information in advance of our call with CLIA.

Please email me at pkimsey@dhs.ca.gov and please also copy the Washington office, sbecker@aphl.org

Many thanks-and have a fine holiday weekend in your neck of the woods.

Paul

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